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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

REXINA MIZE, an individual; MINH NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE LLC; and DOES 1-100, inclusive,

Defendants.

Case No. 2:17-cv-01747-DMG-KS

Honorable Dolly M. Gee

PLAINTIFFS' OPPOSITION TO DEFENDANT MENTOR WORLDWIDE LLC'S MOTION TO DISMISS FIRST AMENDED COMPLAINT

DATE: July 7, 2017
TIME: 9:30 a.m.
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MEMORANDUM OF POINTS AND AUTHORITIES

Plaintiffs Rexina Mize ("Ms. Mize" or "Plaintiff") and Minh Nguyen (collectively "Plaintiffs"), by an through counsel, respectfully submits this memorandum of points and authorities in opposition to the motion to dismiss ("Mentor Memo") filed by Defendant Mentor WorldWide LLC ("Defendant" or "Mentor") to Plaintiffs' First Amended Complaint ("FAC").

I. INTRODUCTION

This case presents claims for injuries allegedly caused by Mentor's MemoryGel Silicone gel-filled breast implants. Silicone gel-filled implants are medical devices that are regulated by the Food and Drug Administration ("FDA"). Ms. Mize was implanted in September 2000 by Dr. Neal Handel, who upon information and belief, has received consulting fees and other payments from Mentor Worldwide LLC.[1]

Mentor seeks to have the entirety of the FAC dismissed under Federal Rule of Civil Procedure 12(b)(6), arguing that all the claims made therein are either expressly or impliedly preempted. These arguments are not compelling and Mentor has failed to offer sufficient evidence to meet its burden. Because the implants at issue were not approved through the Premarket Approval Process at the time Ms. Mize was implanted, the arguments made by Mentor are inapposite and its Motion to Dismiss should be denied.

In addition, Ms. Mize's claims focus on the defective manufacturing of the breast implants, failure to warn of these defects, breach of implied warranty, and Mentor's repeated, systemic, and continuous failure to follow the requirements imposed by the FDA. Ms. Mize's claims parallel, rather than add to, the FDA's requirements, and are, therefore, not expressly preempted by federal law. Instead, the Medical Device Amendment ("MDA"), codified as 21 U.S.C. § 360k(a),

[1] https://openpaymentsdata-origin.cms.gov/physician/355874/payment-information, last checked June 12, 2017.

explicitly provides for the very kind of parallel state law claims that Ms. Mize alleges in her FAC. Also, as discussed in more detail below, the claims made in the FAC do not seek to enforce federal regulations and, thus, are not impliedly preempted. The Motion to Dismiss should be denied, as these claims are adequately pled.[2]

Further, it must be noted at the outset that many of the details regarding Defendant Mentor's allegedly wrongful conduct can only be obtained through discovery, which has yet to take place. As stated by one commentator: "Put simply, plaintiffs need the facts to get discovery, but they need discovery to get the facts."[3]

II. FDA REGULATION OF SILICONE GEL-FILLED BREAST IMPLANTS

Under the MDA to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, the FDA was given the authority to regulate breast implants.[4] Silicone breast implants were marketed in the U.S. through 1991, at which time the FDA investigated whether the data received from the manufacturers was sufficient to establish that silicone gel-filled breast implants were safe and effective. In 1992, the FDA called for a voluntary moratorium on the use of silicone gel-filled breast implants until new safety information could be reviewed. After reviewing this additional information, the FDA lifted the voluntary moratorium to allow for silicone gel-filled breast implants to be implanted in clinical studies for: reconstruction after mastectomy; correction of congenital deformities; or, replacement of implants which had ruptured. The FDA denied applications for using silicone gel-filled breast implants for augmentation.

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[2] As Ms. Mize's claims are not preempted, Plaintiff Minh Nguyuen's loss of consortium claim also survives.

[3] Cameron T. Norris, *Drugs, Devices & Discovery: Using Fee-Shifting to Resolve the Twombly/Iqbal Problem for Parallel Claims Under the FDCA*, 70 Food and Drug Law Journal 187, 194 (2015).

[4] A detailed chronology regarding FDA regulation of breast implants is at: "FDA Breast Implant Consumer Handbook – 2004 - TIMELINE OF BREAST IMPLANT ACTIVITIES" available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064242.htm (last accessed May 31, 2017).

In 2000-2001, the FDA approved Mentor Corporation's[5] application for an Investigation Device Exemption ("IDE")[6] which, despite the existing moratorium, allowed it to use silicone gel-filled breast implants in a limited number of augmentation, reconstruction, and revision patients. As Ms. Mize received her implants in September 2000, Mentor asserts that she must have been part of an IDE study. *See*, Memorandum of Points and Authorities in Support of Mentor's Motion to Dismiss ("*Mentor Memo*.") at pg. 3. Plaintiff is without sufficient information to either admit or deny this assertion, as all information regarding the IDE studies is in the exclusive control of Mentor or the FDA and is not accessible by Ms. Mize.

On December 12, 2003 Mentor submitted a PMA application for its MemoryGel Silicone Breast Implants to the FDA which was approved on November 17, 2006. *Mentor Memo.* at pg. 4. It is undisputed that when Ms. Mize was implanted, the PMA application had not even been filed.

III. LEGAL STANDARD

Mentor seeks dismissal of the FAC under FRCP 12(b)(6). *Mentor Memo. at pg. 1*. In order to satisfy a challenge, a complaint need only allege enough facts to state a claim to relief that is plausible on its face, or sufficient facts to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly* (2007) 550 U.S. 544, 547; *Id*. at 555. "A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint." *Philippe Charriol International Limited v. A'lor International Limited* (S.D. Cal., Nov. 5, 2013, No. 13CV1257-MMA (BGS)) 2013 WL 12080221, at *4. "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of [its] entitlement to relief requires more than labels and conclusions, and

[5] Mentor Worldwide, LLC is the successor in interest to Mentor Corporation. As used herein, the term "Mentor" includes both Mentor Worldwide, LLC and Mentor Corporation.

[6] "An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA." https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/ (last accessed May 31, 2017).

a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." *Id.*, citing *Bell Atlantic Corp. v. Twombly* (2007) 550 U.S. 544, 555. Plaintiffs have far exceeded this standard.

"All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." *Cahill v. Liberty Mut. Ins. Co.* (9th Cir. 1996) 80 F.3d 336, 337–38. "A complaint should not be dismissed unless a plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at 338.

"When ruling on a motion to dismiss, the Court *may* consider the facts alleged in the Complaint, documents attached to the Complaint, documents relied upon but not attached to the Complaint when authenticity is not contested, and matters of which the Court takes judicial notice." *Marsh v. San Diego County* (S.D. Cal. 2006) 432 F.Supp.2d 1035, 1043. Plaintiffs concurrently filed a Motion to Strike paragraphs 3-5 and the corresponding Exhibits A-C of the Declaration of Mollie F. Benedict filed by Defendant in support of its Motion to Dismiss, as they are inadmissible for the facts of the matters asserted and cannot be relied upon for purposes of the 12(b)(6) motion since they were not alleged in the FAC, attached to it, or judicially noticed. Mentor asks for the FAC to be dismissed based on evidence not within the four corners, since IDEs are not publicly accessible, which is not allowed.

The FAC adequately sets forth detailed factual allegations with sufficient particularity known at this time to state cognizable legal claim sufficient to allow Mentor to respond. Mentor argues that the claims made in the FAC are all preempted. In considering this argument, the Court should bear in mind that "pre-emption is a demanding defense," and Mentor has the burden of demonstrating that it applies. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) ("Wyeth failed to demonstrate that it was impossible for it to comply with both federal and state requirements").

Because the Motion to Dismiss is procedurally defective and Mentor has failed to carry its heavy burden of establishing that all the claims made in the FAC are preempted, this Court should deny this Motion and allow the case to proceed.

III. ARGUMENT

A. The Motion to Dismiss Should be Denied Because Mentor has Presented No Admissible Evidence In Support of Its Preemption Argument to Meet Its Burden.

The affirmative defense of preemption is based on Article VI of the U.S. Constitution, also known as the Supremacy Clause[7]. Under Fed. R. Civ. P. 8(b)(1)(A) a defendant "must . . . state in short and plain terms its defenses to each claim." Because it is an affirmative defense, the defendant bears the burden of proving that a claim is subject to preemption. See *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013) (en banc) ("*Stengel*"). And while a court may rule on the affirmative defense of preemption at the motion to dismiss stage, it may only do so when the complaint itself establishes the facts upon which the preemption defense rests. There are no facts within the FAC which would allow Mentor to assert a preemption defense.

The Court is limited to considering only the matters set forth in the FAC in ruling on Mentor's Motion. While a court ruling on to dismiss for failure to state a claim is "generally limited to the face of the complaint, [it may also consider] materials incorporated into the complaint by reference, and matters of which [the court] may take judicial notice". *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012).

Mentor has requested that this Court take judicial notice of certain FDA documents. *See*, *Request for Judicial Notice*, [Dock. No. 27] ("RJN"). In its RJN, Mentor requests that this Court take notice of four documents from the website of

[7] The Supremacy Clause states that federal law "shall be the supreme Law of the Land ... and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

the FDA.[8] Plaintiffs do not dispute that this Court may take judicial notice of public records, including those on the FDA website. Fed. R. Evid. 201. However, these documents are immaterial to the issues raised by Mentor in its Motion to Dismiss, as they all relate to the 2006 PMA approval and have no bearing on issues related to the IDE in which Mentor asserts Ms. Mize was a patient.[9]

Mentor bases its preemption argument on the assertion that "Plaintiff Rexina Mize was surgically implanted with Mentor MemoryGel Silicone Breast Implants in September 2000 as part of Mentor's Core Study. See FAC ¶¶ 135–136." *Mentor Memo. at pg. 2*. However, contrary to Mentor's assertion, there are no facts set forth in paragraphs 135 or 136 of the FAC, or for that matter anywhere within the FAC, which refer to the manner in which Ms. Mize came to be implanted with the Mentor implants or state that she received her implants through the IDE.

The entire factual basis for Mentor's preemption argument is that "[i]n August 2000, the FDA approved Mentor's IDE study (i.e., Core Study)." *Mentor Memo. at pg. 3*. Based upon this assertion and the date that Ms. Mize received her Mentor implants, Mentor deduces that she must have been part of the Core Study as her implantation occurred after the Core Study began but before the PMA approval in 2006. Mentor asserts that "Plaintiff's FAC acknowledges that at the time the Mentor Silicone Breast Implants were implanted in Plaintiff for augmentation in September 2000, they could *only* be implanted pursuant to the IDE Core Study. *See Id.* at ¶ 9." *Id*. However, Plaintiff never affirmatively states that she was part of the Core Study in her FAC and the portion of the FAC which Mentor seeks to rely on merely states that the Core Study occurred.

[8] *See* Docket No. 27, 27-1, 27-2. 27-3. 27-4.

[9] Mentor has also filed the Declaration of Mollie F. Benedict in Support of Mentor Worldwide LLC's Rule 12(b)(6) Motion to Dismiss Plaintiffs' First Amended Complaint [Dock. No. 26-1] filed May 16, 2017. That declaration attaches documents from three unrelated cases. Plaintiffs have moved to strike portions of that Declaration and assert that the contents of the orders upon which Mentor seeks to rely are inadmissible hearsay. See, Motion to Strike Portions of the Declaration of Mollie F. Benedict in Support of Mentor Worldwide LLC's Rule 12(b)(6) Motion to Dismiss Plaintiffs' First Amended Complaint, filed contemporaneously with this Opposition.

Mentor attempts to gloss over the fact that there is no evidence before the Court that Ms. Mize received her Mentor implants as part of the Core Study with its *ipse dixit* assertion that she was a member of that study. However, Mentor has not provided any information to support this assertion. The information surrounding Mentor's IDE protocol and Plaintiff Rexina Mize's alleged participation in the Core Study is in the sole custody and control of Mentor and the FDA. Accordingly, the factual premise upon which Mentor bases its preemption defense is flawed.

The decision in *Caccia v. Biomet, Inc*., No. 3:13–CV–73 RLM, 2013 WL 4502211 (N.D. Ind. Aug. 21, 2013) is instructive on this point. Just as in the present case, in *Caccia* the medical device manufacturer alleged the claims were preempted. While the court agreed that preemption may be applied in a case involving an IDE, the court ruled that the claims were not preempted because the plaintiff was not a participant in the clinical trial for which the IDE device was approved. Following this reasoning, the claims made in the FAC are not preempted as there is no evidence that Ms. Mize was enrolled in the IDE Core Study. Determining whether Ms. Mize was a participant in the Core Study will involve a factual inquiry, which is appropriate for discovery.

Even if Mentor was able to establish that Ms. Mize was part of the IDE Core Study, it still cannot present its preemption defense by way of a 12(b)(6) Motion as that would require this Court to look at evidence outside the pleadings.

In *Burgos v. Satiety, Inc*., No. 10–CV–2680, 2011 WL 1327684 (E.D.N.Y. April 5, 2011) the court addressed many of the issues presented in Mentor's pending Motion to Dismiss. The *Burgos* case involved claims related to a medical device which was available under an IDE. In denying in part the manufacturer's motion to dismiss, that court stated: "*Twombly* and *Iqbal* do not require that Burgos plead her case with particularity—all she must do is provide enough facts to support a plausible inference that Satiety has violated the terms of its IDE. [citations]. This she has done. To require her to do more would be to 'turn *Twombly* into an

insurmountable hurdle' for a plaintiff whose claims rest on the terms of confidential documents not available in the public sphere. [citation]." *Id*. at *4.[10]

Mentor has failed to offer any evidence of the IDE requirements, and fails to ever state what specific requirements it claims apply, and thus cannot assert that the claims made in the FAC "would impose manufacturing or labeling requirements different from, or in addition to, those approved by the FDA through the IDE process and therefore are preempted []." *Mentor Memo. at pg. 1*. (See, *Poll v. Stryker Sustainability Solutions, Inc.*, 2014 WL 199150 CIV 13–440–TUC–CKJ (D. Az. Jan. 17, 2014) (approval letter, PMA, labeling, and supplements are available on the FDA's website.). In fact, Mentor merely recites a litany of general requirements and guidelines governing IDE's, but never specific protocols or requirements for its own IDEs. *Mentor Memo. at pgs. 3-4*. Therefore, it cannot argue that the allegations in the FAC conflict with, differ from or are greater than the FDA requirements for the IDE, assuming that Ms. Mize was part of the IDE, as that information is not before the Court.

B. The Motion to Dismiss Should be Denied, as Plaintiff Has Properly Pled Non-Preempted Claims.

As set forth in her First Amended Complaint, the allegations against Mentor are properly pled. *FAC ¶ 135.* Since June 24, 1988, the FDA has categorized breast implants as Class III medical devices.[11] In 1992, the FDA determined that Mentor's MemoryGel Silicone Gel Breast Implants could no longer be marketed in the U.S., with the exception of use in reconstruction and revision patients. *FAC* ¶ 49. Three years after submitting the application, the FDA approved Mentor's application for

[10] With regard to the issues presently before this Court, *Burgos* held that "[plaintiff] alleges that the TOGA device was 'manufactured in violation of the terms, conditions, standards and specifications of the [IDE] secured by Satiety.' [] She does not allege how the TOGA device's manufacture violated the IDE, nor does she specify the terms, conditions, standards, or specifications that she claims were violated. However, at this stage of the proceedings she cannot reasonably be expected to do so, because the information she requires to provide the requisite degree of specificity—the IDE documentation submitted by Satiety to the FDA—is confidential and not available to the public. See 21 C.F.R. § 812.38. If she had the same information that Satiety has, she might well be able to specifically allege ways in which Satiety was negligent in its manufacture of the TOGA device used in her procedure." *Id*.

[11] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064242.htm (last accessed May 24, 2017).

premarket approval ("PMA") to again sell silicone breast implants in the U.S., subject to certain conditions and ongoing obligations. *FAC* ¶ 68. This approval was over six years after Ms. Mize was implanted. Based upon the date of her surgery, and the fact that her implanting surgeon has been paid consulting fees by Mentor Worldwide, LLC, Defendant concludes that Ms. Mize was part of a clinical study, referred to as the "Core Study," for which an IDE exists.[12] To date, there is no affirmative documentation that Ms. Mize was part of the "Core Study," either publically available or produced by Mentor.

C. Plaintiff's Claims Are Not Barred By Federal Preemption.

1. There Is A Strong Presumption Against Preemption.

The majority of the arguments made by Mentor are based on their contention that the state law claims made in the FAC are preempted. However, in making these arguments, Mentor fails to acknowledge that there is a presumption against preemption. In analyzing the scope of preemption, a court's must "start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted). The party "seeking to invalidate a state law based on preemption bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplant state law." *Stengel v. Medtronic Inc*., 704 F.3d 1224, 1227 (9th Cir.2013) (en banc) (internal quotation marks omitted).

The presumption against preemption applies to federal statutes, including 21 U.S.C. § 360k (the MDA). "It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,'" *Lohr* (1996) 518 U.S. at 487 (citations omitted). Mentor's Motion

[12] "An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data." https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/. (Last accessed May 24, 2017).

fails to overcome the strong presumption against preemption because they failed to establish that Congress intended to bar Plaintiff from redress for injuries caused by Defendant's violations of its requirements.

2. Plaintiff's Claims are Not Expressly Preempted.

Defendant argues that all of Ms. Mize's claims are expressly preempted, alleging that IDEs are entitled to *Riegel* preemption, as they seek to "impose manufacturing or labeling requirements different from, or in addition to, those approved by the FDA through the IDE process []." *Mentor Memo. at pg. 1, 12*. In *Riegel v. Medtronic, Inc.* 552 U.S. 312 (2008) the Court set out the two step analysis to determine whether a state law claim is preempted. Under *Riegel*, the court must first "determine whether the Federal Government has established requirements applicable to" the device at issue. If so, then the court must determine whether the "common-law claims are based upon requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id*. at 321-22.

Applying this analysis in the present case, it is clear that the claims made in the FAC are not expressly preempted, because they are not "'different from, or in addition to' the requirements imposed by federal law." *Id.*; 21 U.S.C. § 360k(a)(1). Stated another way, claims that challenge the safety and efficacy of a Class III device *are permitted* as long as they are not "different from, or in addition to" federal requirements.[13]

Defendant's blanket conclusory statement that *Riegel* stands "unequivocally" for the proposition that state-law claims are preempted for devices subject to the PMA process is a misconstruction of *Riegel* and its progeny, which limited preemption to manufacturers who *comply* with federal law, but denies it to those

[13] There is no express preemption in the MDA that would prevent Plaintiff from bringing state law claims against Mentor for the manufacture of a defective device, so long as claims against a manufacturer parallel, rather than add to, the federal requirements. In *Stengel v. Medtronic, Inc*. (2012), 704 F.3d 1224, the Ninth Circuit Court of Appeals made it clearer than ever that courts within the Ninth Circuit should take an expansive view of what constitutes a "parallel" claim.

who *violate* federal law. *Mentor Memo.,* pg. 9:15; 10:8; *Riegel,* 552 U.S. at 330; *Bausch v. Stryker Corp.* (7th Cir. 2010) 630 F.3d 546, 552, 553.

Courts hearing the same arguments for preemption of Class III medical devices have found that state law claims are not preempted. Specifically, Circuit courts "have uniformly held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty "parallels" the federal-law duty under the MDA." *Stengel v. Medtronic Inc.,* (9th Cir. 2013) 704 F.3d 1224, 1231.

In *Stengel*, the Ninth Circuit held that the MDA did not preempt the plaintiffs' state-law failure-to-warn claim. *Id.* at 1234. The court held, under *Lohr,* and *Riegel,* that a failure to warn claim brought for injuries related to a PMA-approved, Class III medical device was not expressly or impliedly preempted by the MDA. *Stengel* further held that there is no federal preemption under the MDA for a claim that a medical device manufacturer has failed in its "continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." *Id.* at 1232. A failure to warn the FDA constitutes a violation of the FDA's own regulations, which require a manufacture to file an Adverse Event Report it if learns of information "'reasonably suggest[ing]" that one of its devices '[m]ay have caused or contributed to a death or serious injury.'" *Id.* at 1234.

As with Arizona law, which was the state law at issue in *Stengel,* California law creates a duty to warn parallel to 21 C.F.R. § 803.50(a), and a device manufacturer can be found liable if it "did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Anderson v. Owens-Corning Fiberglass Corp.,*(1991) 53 Cal. 3d 987,

1002. A manufacturer owes a foreseeable user of its product a duty to warn of risks of using the product. *Wright v. Stang Manufacturing Co.*, 54 Cal. App. 4th 1218, 1235, 63 Cal. Rptr. 2d 422, 433 (1997).

The *Eidson* court concluded that "most lower courts—both federal and state—that have analyzed and applied *Stengel* to California state law failure to warn claims premised on a failure to report to the FDA have held that the claims escape both express and implied preemption." *Eidson v. Medtronic, Inc.* (N.D. Cal. 2014) 40 F.Supp.3d 1202, 1233.

The Court in *Coleman v. Medtronic, Inc*. (2014) 223 Cal.App.4th 413, 428-29 followed the *Stengel* reasoning and found that the plaintiff's failure to warn claim based on a failure to file adverse event reports with the FDA was not subject to express or implied preemption, and that the Fifth and Ninth Circuits have determined that state law claims based on failure to file adverse event reports with the FDA are not subject to preemption. (Coleman's claim is a strict liability failure to warn claim under California law, like in the above-entitled action).

Similarly, the Fifth Circuit has held that a failure to warn claim is not expressly preempted to the extent it is based on the manufacturer's violation of applicable FDA regulations requiring accurate reporting of serious injuries from the device, since the claim did not impose additional or different requirements to the federal regulations, but rather was parallel to federal requirements. *Hughes v. Boston Scientific Corp.* (5th Cir. 2011) 631 F.3d 762, 771. The *Hughes* court also found that invoking the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements was not expressly preempted (finding the MDA codified under § 360k does not preempt use of the negligence per se doctrine). *Id.;* fn. 8.

As noted in *Bausch v. Stryker Corp*. (7th Cir. 2010) 630 F.3d 546, 550, "the Supreme Court has twice addressed the *limited scope* of this preemption provision" under 21 U.S.C. 360k(a), and that, "in fact, the Court's opinions in *Lohr* and *Riegel*

expressly left the door open for state law claims based on violations of federal law." (emphasis added) (citing to *Medtronic, Inc. v. Lohr,* 518 U.S. 470; *Riegel,* 552 U.S. 312).

> The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law. In other words, where state law is parallel to federal law, section 360k does not preempt the claim.

Bausch, 630 F.3d at 552. The *Bausch* court concluded that plaintiff's claims for defective manufacture in violation of federal law were not expressly preempted by § 360k, and that the claims were not expressly preempted to the extent they were based on defendants' violations of federal law. *Id.* at 556. The *Evraets* court noted that "'for a medical device manufacturer to claim the shield of preemption, the manufacturer *must 'play by the rules*.' If the manufacturer subverts the rules and obtains approval to market its product by misrepresenting the risks involved, knowing that this disinformation will ultimately harm patients, the injured party should be entitled to sue." *Evraets v. Intermedics Intraocular, Inc.* (1994) 29 Cal.App.4th 779, 790–91(emphasis added).

In *Chambers*, the MDA did not preempt a state law claim based on manufacturing defect resulting from violations of FDA requirements. *Chambers v. Osteonics Corp.* (7th Cir. 1997) 109 F.3d 1243, 1248. It reasoned that "such a claim should not be preempted because there is no reason to protect a manufacturer who fails to follow the proscribed requirements and procedures for producing a device, even an *experimental device*." *Id*.

In *Mitchell*, the court concluded that to the extent it was alleged that collagen-based products were mislabeled or adulterated because the manufacturer failed to meet labeling and purity standards established by the PMA, such claim was not preempted by the MDA since it would seek merely to enforce federal standard, not to add requirements different from or in addition to it. *Mitchell v. Collagen Corp.*

(7th Cir. 1997) 126 F.3d 902 (negligence claims not preempted if based on claims that manufacturer did not adhere to FDA standards in the premarket approval process).

In *Huggins,* the court held that plaintiffs' claims were not expressly or impliedly preempted as they were premised on conduct that violated FDCA and FDA regulations and thus parallels federal requirements. *Huggins v. Medtronic, Inc.,* 2013 WL 9662701. In *Ramirez,* the court found that § 360k did not foreclose plaintiff's state law theory. *Ramirez v. Medtronic Inc.* (D. Ariz. 2013) 961 F.Supp.2d 977, 993. In *Hornbeck,* the court held that the FDCA did not preempt plaintiffs' claims, which were state-law claims premised on alleged violations of the FDCA. *Hornbeck v. Medtronic, Inc.* (N.D. Ill., June 2, 2014, No. 13 C 7816) 2014 WL 2510817, at *3.

The Supreme Court has heard three cases involving MDA preemption, all of which established that state law tort claims, as long as they are not "different from, or in addition to" federal requirements, will not be preempted by the MDA. In the 1996 decision of *Medtronic v. Lohr,* the court reversed in part dismissal of certain Florida state tort claims against the manufacturer of a Class III device including allegations that the defendant failed to provide adequate warnings of potential risks. *Lohr*, (1996) 518 U.S. 470. The court noted: "Medtronic's argument is not only unpersuasive, it is implausible. Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Id.* at 487. It concluded that the defendant's interpretation of § 360k would have a perverse effect of granting complete immunity to an entire industry that needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use." *Id.* at 487. The Court indicated that Plaintiffs' state-law duties escape preemption because "their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such

as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA." *Id.* at 502.

In the second case, *Buckman,* the court reviewed a state-law tort claim brought against a consultant to a screw manufacturer which assisted the manufacturer in obtaining FDA approval for the use of the screws in spinal surgeries, making the screws a Class III device. In finding implied preemption for the plaintiff's "fraud on the FDA claim" the Court distinguished its holding from *Lohr* by noting that the *Buckman* plaintiffs did not claim any state law causes of action in their complaint. *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 348. Instead, the *Buckman* plaintiffs were concerned with an alleged fraud on the FDA during the approval process which, the court noted, presented a uniquely federal issue.

In *Riegel,* interpreting § 360k, which is extensively discussed in Mentor's Motion to Dismiss, the plaintiffs sued over the failure of Medtronic's catheter. *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312. The plaintiff's state tort claims alleged that the catheter was designed, labeled, and manufactured in a manner that violated New York law. The court held that the plaintiff's state law based claims were preempted because those claims would have imposed on the manufacturer a greater burden than imposed by the FDA approval process. Stated another way, the plaintiffs sought to impose a standard on defendant Medtronic that was 'in addition to' (or more stringent than) those imposed by the federal regulations. While the court found express preemption, it noted that the decision was consistent with *Lohr's* holding that state law claims 'parallel to' federal law would not be preempted, which is the situation presented by Ms. Mize's case. *Id.* at 330.

The above group of preemption decisions from several circuits, including the Ninth, illustrates that state law tort claims, provided that under § 360k they don't 'add to or differ from federal requirements,' will not be preempted under the MDA. Defendant's express preemption argument is a limited reading of the case law,

which concludes that *not all* state law claims are preempted. Since Mentor violated both state and federal law when it failed to report adverse events and failed to properly conduct the IDE clinical studies required by the FDA[14], then Ms. Mize has presented more than a plausible claim that such state law claims are not preempted.

The *Riegel* court gave lower courts clear instructions to allow state law claims to proceed when they are based on claimed violations of federal law, stating "§ 360 does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel,* 552 U.S. at 330. Consequently, a plaintiff can plead parallel claims to survive preemption.

3. Under *Riegel,* Plaintiff's Claims Are Not Expressly Preempted By the MDA, Because Plaintiff Has a Viable Parallel Claims Theory.

Mentor cites to *Burgos* for the argument that "Because IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices, the body of preemption law governing PMA devices applies equally to the IDE device at issue in this case." *Mentor Memo.* At pg. 12:10-13, citing *Burgos v. Satiety, Inc.* (E.D.N.Y., Nov. 30, 2010, No. 10-CV-2680 JG) 2010 WL 4907764, at *2.

As such, we will proceed with a preemption analysis under *Riegel* to demonstrate that Ms. Mize's claims survive. Ms. Mize's allegations are genuinely equivalent because she is not alleging that Mentor should have done anything more than what the FDA requires them to do regarding the IDE or PMA (which notably was not even submitted to the FDA when she had bilateral Mentor silicone gel-filled implants). Ms. Mize asserts that Mentor must abide by the FDA's rules and regulations- by conducting the mandated studies and reporting adverse events- in accordance with its IDE and consequently the PMA. It is precisely those very

[14] While Defendant Mentor argues that Ms. Mize was part of a clinical study, it is Plaintiff's position that Mentor never followed up with Ms. Mize as part of that clinical study, as there is no documentation confirming this, and thus her adverse event reports could not have possibly been reported by Mentor to the FDA.

violations of federal laws and regulations that has created the extent of violations of California state law. Since the state law duties premised on federal violations are "parallel," rather than additional duties, they are allowed.

"*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Riley v. Cordis Corp*. (D. Minn. 2009) 625 F.Supp.2d 769, 777. Ms. Mize has threaded the needle, and is suing for conduct that *violates* the FDCA (so her claims are not expressly preempted by § 360k(a)) and because of parallel violations of California state tort law duties, but not suing *because* the conduct violates the FDCA (so her claims are not impliedly preempted). "The claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Riley*, 625 F.Supp.2d at 777.

In *Riegel*, the Supreme Court established a two-step framework for determining whether § 360k(a) expressly preempts a state law claim. First, the FDA must have established "requirements" applicable to the particular medical device. The premarket approval requirements applicable to Class III medical devices satisfy this first prong. Next, state law claims- established by either statute or common law- are preempted if they impose requirements that relate to safety and effectiveness and are "different from, or in addition to" the requirements under federal law. *See Coleman,* 223 Cal.App.4th at 423–24.

a. Plaintiff's Claims Are Not "Different From, or in Addition to" Federal Requirements.

The primary inquiry for § 360k preemption is whether Plaintiff seeks to enforce state law requirements that are "different from, or in addition to" federal law requirements. Plaintiff acknowledges that the federal government regulates Class III devices, such as breast implants, for the reason that they are a threat to health and safety. However, with this regulation comes federal post-approval requirements for Mentor to uphold. The FDA's PMA approval for Mentor's

MemoryGel Silicone Breast Implants required Mentor to conduct six studies[15], one of which Mentor claims Ms. Mize was included as a participant. Plaintiff did not allege to enforce state laws that were different from, or in addition to, Mentor's post-approval duties. Instead, Plaintiff's state law claims are based on requirements that parallel federal law, and thus not expressly preempted.

Plaintiff alleged negligence and negligence per se claims under California law, claiming Mentor breached its duty of reasonable care by failing to report to the FDA adverse events associated with its Class III MemoryGel Silicone Breast Implants and failed to comply with the PMA. *FAC* ¶ 147- 154. Plaintiff further alleged that Mentor had the ability and duty under state law to report adverse events to ensure its labeling and product was not misbranded (duty to warn the FDA of adverse outcomes) that parallel requirements under federal law. *FAC* ¶ 153-154; Health & Saf. Code, §§ 111440, 111445; 21 U.S.C. § 331. Further allegations in the FAC specify that Mentor's violations of federal regulations constitute violations that parallel state law duties. *FAC* ¶ 170-172[16]. The negligence claim is not expressly preempted because it seeks to hold Mentor accountable only for failing to do what federal law mandates, and nothing more.

Plaintiff alleged strict liability claims for failure to warn and manufacturing defect, claiming that Mentor failed to comply with federal requirements, and thus violated parallel California state law, but state law did not impose any additional or different requirements on Mentor above and beyond what federal law required them to do. *FAC* ¶ 195-224; 232- 235. These claims are not expressly preempted, since they are based on requirements that parallel federal law.

[15] Mentor requested this Court to judicially notice the letter from the FDA dated Nov. 17, 2006 granting the PMA for MemoryGel Silicone Breast Implants. [Dock. 27-1, Exhibit 1 to RJN]. This letter stated that Mentor "agreed to the conditions of approval," which was the performance of six studies. [Dock. 27-1, Exhibit 1 to RJN, pg. 006-008].

[16] FAC ¶ "172. Defendants' conduct also violates their duties under the Sherman Food, Drug, and Cosmetic laws and gives rise to negligence per se. West's Ann. Cal. Health & Safety Code §§ 109875, et. seq.; 111260; 111295; 111300; 111305; 111440; 111445; and 111450."

b. Negligence Per se Claim Survives.

California recognizes the applicability of negligence per se in a broad range of scenarios, including violation of the FDCA. *Dirosa v. Showa Denko K.K.*, 44 Cal. App. 4th 799, 808, 52 Cal. Rptr. 2d 128, 133 (1996). A federal standard in the Act has been adopted as the standard of care in a negligence action. *Id.* A claim may be brought in state court for negligence per se as long as the injury results from "an occurrence of the nature which the… regulation was designed to prevent" and the person suffering the injury "was one of the class of persons for whose protection the… regulation was adopted." Calif. Evid. Code § 669, subd. (a)(s).

Here, Plaintiff alleges violation of the FDA's regulations to limit risk inherent in Class III medical devices, and, as a recipient of one of those devices, Plaintiff is in the class of persons the regulations are meant to protect. Both claims made in the FAC are cognizable under California tort law, and parallel federal requirements.

c. Mentor Failed to Report Adverse Events to the FDA in Violation of Laws And Regulations.

Ms. Mize's FAC alleges a violation of FDA regulations related to the device, predicated on Mentor's failure to report adverse information about its product to the FDA. The FDA has regulations in place requiring the manufacturer to report any information that reasonably suggests that the device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned and that any recurring malfunction would be likely to cause or contribute to a death or serious injury. 21 C.F.R. § 803.50(a); *Stengel*, 704 F.3d at 1226-7; *FAC* ¶ 55, 62, 171. Furthermore, the PMA itself imposed requirements in the form of six follow-up studies, described above and more extensively in the FAC, and Ms. Mize who was allegedly a participant in one of the studies, was never followed-up with by Mentor, making the study insufficient to comply with Mentor's own PMA and federal reporting regulations. It is proof by omission that Mentor did not sufficiently conduct its clinical studies, and should not be entitled to protection from liability.

The FAC alleges that Mentor failed to report adverse events from the six new or ongoing studies beginning before the PMA approval, which were required by the FDA as conditions of approval[17], and all of which would have led to reports suggesting the device's contribution to serious injury: (1) The Core Post-Approval Study showed a follow-up of only 59%, with reporting done only for six of the ten required years. *FAC* ¶ 70, 72. (2) The Large Post-Approval Study only enrolled 41,452 patients, almost 500 fewer than the PMA required. *FAC* ¶ 77-79. By year seven, the overall follow-up rate was *only 20.1%*. *FAC* ¶ 79. (3) The Device Failure Study did not list sample size, results of the data findings, safety findings, recommendations or summary of safety and data or follow-up on the data, and did not list any changes to labeling, all in violation of this condition established in the PMA order. *FAC* ¶ 85. Of the retrieved devices, more than half were outside of the U.S., and only 4% were associated with the post-approval study patients. *FAC* ¶ 83. (4) The Focus Group Study used only 35 women in its study and subsequently ignored their recommendations for labeling changes. *FAC* ¶ 88, 90. (5) For the Informed Decision Study, Mentor did not file a list of the sample size or the patients enrolled, and provided minimal information on the outcome. *FAC* ¶ 93-94. (6) For the Mentor Adjunct Study, the overall patient follow-up rates at Year 1 was 44%, Year 3 was 24.7%, and Year 5 was 13.8%. *FAC* ¶ 97.

These results demonstrate a continual violation of the FDA's requirements. Because of poor follow-up or obfuscation of the data, including failing to follow-up with Ms. Mize, information was not given to the FDA that would have disclosed the product's propensity to cause serious injury. Failure to report leads to the omissions of these events from the FDA's publicly accessible MAUDE database. Plaintiff has not alleged any violation of reporting requirements that are different from or in addition to what was required in the PMA.

[17] *See supra, fn. 15.*

d. Plaintiff Establishes a Causal Nexus Between Her Injuries and Mentor's Violations.

In order to make a cognizable failure to warn claim to survive preemption, the plaintiff is also required to establish a causal nexus between the alleged injuries and the alleged violations. *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1233 (N.D. Cal. 2014). In *Eidson*, after plaintiffs amended their claims to include facts about the nature of defendants' failure to report adverse events, which Ms. Mize has already done, they were able to show that "(1) Defendants underreported adverse events on a large scale, and (2) plaintiffs' surgeons would have had access to adverse reports if they were properly submitted." *Id.* at 1234. The district court held that at the pleading stage, the allegations were sufficient to infer that had defendants made the required reports, physicians would have been put on notice of the dangers of the medical device. *Id.* The plaintiffs' failure to warn claims were not dismissed because they alleged a causal nexus. *Id.*

The FAC alleges in multiple paragraphs that Mentor failed to conduct follow-up with participants enrolled in its clinical studies – which allegedly Ms. Mize was a participant in, and Mentor failed to follow-up with her – and thus Mentor failed to report adverse events to the FDA as required. All six of the studies described above were supposed to support long-term safety, both at the time Ms. Mize was implanted and for future years during which she had her breast implants, but Mentor's poor follow-up rates and inadequate data confirm Mentor's systematic failure to follow IDE and FDA requirements, and further failure to report adverse events which could have been publicly accessed in the MAUDE database, and subsequently analyzed by researchers who identify injury trends and publish articles. *See FAC* ¶ 99[18]. For instance, there would have been adverse event reports

[18] FAC ¶ "100. For instance, halfway through the ten-year prospective post-marketing studies mandated by the FDA, well *over 50% of the 80,000 women in the study groups were dropped* or otherwise eliminated from the studies. Of the patients who were accounted for, *significant numbers reported systemic ailments* which can only be attributed to gel bleed introducing known toxins including silicone, heavy metals and chemicals into their bodies. *Mentor was aware, or should have been aware that the gel contained chemicals and metals toxic to the human body but failed to adequately report that to the FDA* and warn their patients of their dangerous consequences." (emphasis added).

showing the heightened incidences of rupture rates, which Ms. Mize suffered, had Mentor conducted their studies and reported adverse events properly. If Mentor had provided proper clinical study follow-up data and adverse event reports, such as the heightened incidence of rupture rates, Ms. Mize would have understood the breadth, scope, and cause of her injuries much sooner. The voluminous allegations of Mentor's failure to provide the required follow-up data from multiple PMA-dictated studies, along with the fact that Mentor failed to follow-up with Ms. Mize, is enough to survive a motion to dismiss.

e. Plaintiff's Manufacturing Defect Claim is Not Expressly Preempted.

Under California law, "a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result." *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 429. A defective manufacturing claim "is not preempted insofar as it alleges that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law." *Funke v. Sorin Group USA, Inc.* (C.D. Cal. 2015) 147 F.Supp.3d 1017, 1026-27 ("at the pleading stage it need only be plausible that a product defect at issue was the result of defective manufacturing."). The district court agreed with *Bausch's* conclusion that district courts "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Id.* at 1027; *Bausch v. Stryker Corp.* (7th Cir. 2010) 630 F.3d 546, 558.

In *Hofts*, the district court concluded that manufacturing defect claims were not preempted, and explained that the plaintiff was basing claims on allegations that the manufacturer failed to meet the FDA's requirements, not on the basis that it

failed to depart from or exceed those requirements. *Hofts v. Howmedica Osteonics Corp.* (S.D. Ind. 2009) 597 F.Supp.2d 830, 836 (jury could find the manufacturer failed to adhere to the FDA's manufacturing requirements without imposing different or additional requirements). Similarly, the *Warren* court concluded that plaintiffs' claims were not preempted because they did "not impose any additional duties on defendant; plaintiffs' claims stem solely from defendant's alleged violation of federal regulations." *Warren v. Howmedica Osteonics Corp.* (E.D. Mo., Dec. 8, 2010, No. 4:10 CV 1346 DDN) 2010 WL 5093097, at *6.

Ms. Mize's manufacturing defect claim survives preemption for the same reason as her failure to warn claim. The MDA does not expressly preempt state-law manufacturing defect claims because they are neither 'different from nor in addition to' the requirements specified in the IDE studies or PMA. Ms. Mize alleges that the PMA includes specifications with respect to the manufacture of the implant. *FAC* ¶ 234. The FAC further alleges that the FDA also has Quality System Regulations and Current Good Manufacturing Practices in place that required Mentor to test products for compliance with specifications, to document and check compliance before they were placed on the market, and to identify and all products that failed to conform with product specifications. *FAC* ¶235. Plaintiff also cites to FDA Form 483s, which lists deviations from federal laws and regulations. *FAC* ¶ 114-120. While Mentor argues that five of the six Form 483s cited occurred after Plaintiff's implant date, they fail to acknowledge that those are the Form 483s that Plaintiff could obtain prior to initiating discovery. *Mentor Memo,* pg. 19. Discovery will reveal further violations for all years of production of the silicone breast implants, including those produced during the moratorium and used for IDE purposes.

The product implanted in Ms. Mize's body was one that differed from the manufacturer's intended result. *FAC* ¶ 234. Specifically, the rupture, leakage, and bleeding of silicone, due to porous or weak containment in the implant shell, was inconsistent with specifications and conditions of the product submitted to the FDA

for PMA approval. *Id.* The FAC further alleges that a causal nexus existed between these defects and the injuries suffered by Ms. Mize. *FAC* ¶ 238-39.

It is clear from the allegations in the FAC that Plaintiff's state law claims do not impose additional or different requirements on Mentor, and stem from its violations of federal regulations, and thus are not preempted.

4. Plaintiff's Claims Are Not Impliedly Preempted.

Defendants alternatively argue that state law claims are impliedly preempted, relying on *Buckman's* "fraud on the FDA" theory, and barred by 21 U.S.C. § 337(a). *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Mentor Memo,* pg. 13. In addition to there being no express preemption of Ms. Mize's claims, there is also no implied preemption. *Buckman* does not foreclose claims based on any conduct that violates the FDCA.

In *Buckman*, patients claimed they suffered injuries from implantation of orthopedic bone screws into their spines, a Class III medical device. The patients settled their claims against the device manufacturer and proceeded on a suit solely against a regulatory consultant they alleged made fraudulent representations to the FDA in the PMA process. The Supreme Court held that the "fraud on the FDA" claims conflict with, and thus are impliedly preempted by the FDCA as amended by the MDA. *Buckman*, 531 U.S. at 348. This is not the case with Ms. Mize's allegations. Plaintiff, in no way, attempted to enforce or usurp the FDA's regulatory authority. Plaintiff merely wanted Mentor to *abide by* FDA regulations and the clinical studies that were conditions in the PMA. Plaintiff also did not base her tort claims solely on violations of federal law. Rather, Plaintiff was enforcing state tort law claims, as aforementioned, that occurred *because* of Mentor's violation of their PMA and the FDCA.

In *Stengel*, the Ninth Circuit Court of Appeals determined that the plaintiffs' claims, which paralleled state tort law, were not expressly or impliedly preempted. *Stengel,* 704 F.3 at 1223. The Ninth Circuit decided that a state law failure to warn

claim could be made independent of the FDA's pre-market approval process and that claims of a failure to pass along warnings to the FDA did not constitute a "fraud on the FDA" for the purposes of *Buckman* preemption. *Id.*

In *Eidson,* the district court stated "a claim is impliedly preempted if it is cognizable only by virtue of the provisions of the FDCA itself and would not be independently viable under state law; conversely, a state law cause of action escapes implied preemption if it would state a claim under state law even in the absence of the FDCA. *Eidson,* 40 F.Supp.3d at 1216. In *Riley,* the court reasoned that "the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Riley v. Cordis Corp.* (D. Minn. 2009) 625 F.Supp.2d 769, 777.

Ms. Mize's claims are not impliedly preempted because she is not making a "fraud on the FDA" claim, and they are based on viable state-law tort causes of action which exist even in the absence of the FDCA.

D. Plaintiff Minh Nguyen's Loss of Consortium Claim Survives.

As a result of Plaintiff Ms. Mize's claims escaping express and implied preemption, her spouse's loss of consortium claim must survive. As in *Hernandez,* "because the Court has not dismissed all of Plaintiffs' other claims and Defendant offers no other basis for dismissing the loss of consortium claim, its motion to dismiss this claim is denied." *Hernandez v. Monsanto Company* (C.D. Cal., July 12, 2016, No. CV 16-1988-DMG (EX)) 2016 WL 6822311, at *9.

IV. CONCLUSION

Based on the above, Plaintiffs respectfully request that the Court enter an order denying Defendant Mentor Worldwide LLC's Rule 12(b)(6) Motion to Dismiss. Alternatively, Plaintiffs request leave to amend the First Amended Complaint.

Date: June 15, 2017

By: /s/ Jaime E. Moss

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CERTIFICATE OF SERVICE

I hereby certify that, on June 15, 2017 a copy of the foregoing **PLAINTIFFS' OPPOSITION TO DEFENDANT MENTOR WORLDWIDE LLC'S MOTTION TO DISMISS FIRST AMENDED COMPLAINT** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Date: June 15, 2017

By: /s/ Jaime E. Moss

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